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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/524,716	03/14/2000	Bryan W. Wolf	6671.US.01	8310

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EXAMINER

CHOI, FRANK I

ART UNIT PAPER NUMBER

1616

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/524,716

Applicant(s)

WOLF ET AL

Examiner

Frank I Choi

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/7/02, 1/8/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18, 19 and 22 is/are allowed.
- 6) ☒ Claim(s) 1-17, 20, 21, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Allowable Subject Matter

Claims 18, 19 and 22 are allowed subject to update of the prior art search herein.

Terminal Disclaimer

The terminal disclaimer filed on 1/8/2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat. No. 6,248,375 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17, 20, 21, 23, 24 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kaufman (U.S. Pat. 5,843,921) for the reasons of record set forth in the prior Office Action and the further reasons below.

Kaufman was discussed in the prior Office Action and the same is incorporated herein.

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

It is not clear from Applicant's arguments how the claims avoid the express disclosure of Kaufman. Further, in a 102/103 inherency based rejection, the *Graham v. John Deere* factors are not applicable, as such, Applicant's arguments relative to unexpectedness do not appear to overcome the rejection herein. Thus, the rejection under 102/103 is maintained.

Claims 1-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Paul et al. (U.S. Pat. 5,292,538).

Paul et al. expressly discloses a carbohydrate source comprising about 5-45% fructose and about 55-95 % glucose polymers which is assimilated immediately upon ingestion and compositions containing said carbohydrate source, lipids, proteins, minerals and vitamins (Column 4, lines 30-43, Column 9, lines 56-68, Column 10, lines 56-68, Column 11, lines 1-44, Column 12, lines 1-44, Formulations I-VII) falling within the scope of applicant's claims.

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 1-17, 20,21,23,24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paul et al. (U.S. Pat. 5,292,538) in view of in view of Kaufman (U.S. Pat. 5,843,921).

Paul et al. teaches a carbohydrate source comprising about 5-45% fructose and about 55-95 % glucose polymers which is assimilated immediately upon ingestion and compositions containing said carbohydrate source, lipids, proteins, minerals and vitamins (Column 4, lines 30-43, Column 9, lines 56-68, Column 10, lines 56-68, Column 11, lines 1-44, Column 12, lines 1-44, Formulations I-VII). It is taught that glucose stimulates insulin whereas fructose does not

require insulin, promotes a more rapid emptying of the stomach such that there is a reduced feeling of bloating and more rapid delivery of nutrients (Column 3, lines 53-65).

Kaufman teaches that fructose and slowly metabolized complex carbohydrate, such as uncooked corn starch, helps to stabilize glucose levels and that fructose can be used as a sweetener in compositions intended for consumption by persons suffering from diabetes and an example containing fructose, corn starch, polydextrose, fat sources and protein source is taught which was effective in reducing the incidence of fluctuations in glucose levels and hyperglycemia after eating. (Pages 4-12). It is taught that the composition contains about 10-25% calories from fat and 10-25% calories from protein and about 50-75% calories are from carbohydrates (pg. 7).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a method of providing nutrition to a individual with diabetes or for blunting the postprandial glycemic response by enterally administering a composition containing fructose and glucose polymers. However, the prior art amply suggests the same as it is known that fructose is suitable for use as a sweetener in composition intended to be consumed by diabetics. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to add lipids, minerals, vitamins and other nutrients as needed, including amounts within the scope of the claimed invention, depending on the nutritional needs of the diabetic patient. Finally, one of ordinary skill in the art would have expected that the Paul et al. compositions would be suitable for use in diabetics as said compositions contain fructose and glucose polymers as the primary carbohydrate source instead of glucose.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 1/7/2002 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

April 3, 2002


JOHN PAK
PRIMARY EXAMINER
GROUP 1600

